REMARKS

Status of Claims

Claims 1-23 are pending and under consideration.

Restriction Requirement under 35 U.S.C. §§ 121 and 372

The Office requires restriction under 35 U.S.C. §§ 121 and 372 between the following three groups of claims:

Group I - Claims 1-17 and 22, drawn to a method of analyzing a biological sample in connection with acute cardiovascular disease; classified in class 435, subclass 7.21, for example. (A 1st method employing a special technical feature).

Group II - Claims 18-19, drawn to kits comprising reagents for analyzing cardiovascular diseases; classified in class 422, subclass 61, for example. (A 1st product comprising a special technical feature).

Group III - Claims 20-21 and 23, drawn to therapeutic methods monitoring acute cardiovascular diseases; classified in class 424, subclass 9.1, for example. (A 2nd method employing the special technical feature).

According to the Office, the inventions listed as Groups I-III "are not so linked as to form a single general inventive concept under PCT Rule 13.1" because they allegedly lack a technical relationship involving a special technical feature, as required by PCT Rule 13.2. (Office Action, page 2.) Specifically, the Office contends that the technical feature linking the inventions of Groups I-III "is the utility of biomarkers like sCD40L and CRP in acute cardiovascular diseases," and that this technical feature is disclosed in Garlichs C.D. et al., "Patients with Acute Coronary Syndromes Express Enhanced CD40 Ligand/CD154 on Platelets," Heart, 86: 649-655 (2001) ("*Garlichs*"). (*Id.*) The Office concludes that since the technical feature linking Groups I-III allegedly "is not a contribution over the prior art," it does not link the inventions of Groups I-III so as to form

a single general inventive concept. (*Id.*) Applicant respectfully disagrees and traverses the restriction requirement for the following reasons.

The specification teaches that a special technical feature linking the inventions of Groups I-III is the utility of biomarkers, such as sCD40L, PAPP-A, and P1GF, for the diagnosis or prognosis of acute cardiovascular diseases. (*See* Specification, *e.g.*, at Abstract.) In contrast, *Garlichs* merely discloses that "CD40L/CD154 on platelets and soluble CD40L/CD154 are raised in patients with unstable angina and myocardial infarction." (*See* Abstract.) *Garlichs* does not teach or suggest the use of sCD40L for the diagnosis or prognosis of acute cardiovascular diseases. Thus, the inventions of Groups I-III share a special technical feature over the prior art and, therefore, form a general inventive concept. For at least these reasons, all of claims 1-23 should be examined together according to PCT Rule 13.2.

Moreover, for a restriction requirement to be proper under U.S. Patent Law, there must be a serious search burden on the Examiner. (*See* M.P.E.P. § 803.) "If the search and examination of all the claims in an application can be made without serious burden, the examiner ***must*** examine them on the merits, even though they include claims to independent or distinct inventions." (*Id.*; emphasis added). In this case, the Office has failed to demonstrate that searching Groups I-III together would impose a serious burden.

In fact, a search for these groups would be largely coextensive, since the same search terms would be used to search the prior art. For instance, because the same special technical feature links all of Groups I-III, key words may be chosen that incorporate the inventions in all of these claim groups without serious burden.

Moreover, examining these groups separately would impose extra costs and delays on the Office due to the duplicative search and examination that would be involved. Accordingly, Applicant respectfully submits that examining all the claims of Groups I-III together would not impose a serious burden on the Examiner.

For at least these reasons, Applicant respectfully requests that the Restriction Requirement be withdrawn and that all of claims 1-23 be examined together. In order to be fully responsive, however, Applicant elects Group III (*i.e.* claims 20-21 and 23) for further consideration in case the Restriction Requirement is maintained.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this Restriction Requirement and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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